

REMARKS

Introductory Comments:

Claims 1, 3, 4, 6-8 and 32-35 were examined in the Office Action under reply. Claims 32-35 are indicated as allowable and claims 1, 3, 4 and 6-8 stand variously rejected under (1) 35 U.S.C. §112, first paragraph (claims 1, 3, 4, and 6-8); (2) 35 U.S.C. §112, second paragraph (claims 1, 3, 4, 6-8 and 32-35); and (3) 35 U.S.C. §102(b) (claims 1, 4 and 6-8). These rejections are respectfully traversed as discussed more fully below.

Applicant notes with appreciation the withdrawal of the previous rejections under 35 U.S.C. §112, second paragraph and 35 U.S.C. §102(e).

Overview of the Above Amendments:

Claims 1 and 32 have been amended to recite the subject invention with greater particularity. Specifically, claims 1 and 32 now refer to Figure 2A rather than Figure 2B. Additionally, claim 1 has been amended to recite “15 amino acids” rather than “15 nucleotides” as the fragment referred to is a polypeptide fragment. Finally, claim 1 has been amended to recite that the immunological response “comprises the ability to elicit the production of neutralizing antibodies against *C. parvum*.”

Support for the amendments can be found throughout the specification at, e.g., page 10, lines 22-24; page 16, lines 23-27; page 23, lines 22-23; and in Example 5. The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications containing the unamended claims.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 1, 3, 4 and 6-8 remain rejected under the written description clause of 35 U.S.C. §112, first paragraph. In the previous response, applicant directed the Examiner’s attention to Example 14 of the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement (“the Revised Interim Guidelines”). This example specifically examines a claim reciting variants of a specified sequence that are “at

least 95% identical” to the reference sequence and that “catalyze the reaction” of A to B. The Examiner agrees with applicant’s assessment of Example 14 and states:

Example 14 clearly identifies the members of the genus by those which have a particular activity (i.e., catalyze the reaction of A to B). One of skill in the art would be able to readily identify which members of the genus possessed the claimed activity given that assays for detecting this activity are well known in the art.

(Office Action, page 3). The Examiner, however, argues applicant’s recitation of “an equivalent or enhanced immunological response” does not provide “any activity of the protein” and that there is no “clear indication of how ‘equivalent or enhanced immunological response’ is measured.” Office Action, page 3. However, applicant respectfully submits the application indeed complies with the requirements of 35 U.S.C. §112, first paragraph.

In particular, the claims have been amended to recite that the immunological response “comprises the ability to elicit the production of neutralizing antibodies against *C. parvum*.” Assays for determining the ability to generate neutralizing antibodies are well known in the art. In fact, Example 5 of the application provides one such method. Thus, the claims indeed recite the distinguishing attributes shared by the members of the genus. As in Example 14 of the Revised Interim Guidelines, applicant has specified a structure along with a common attribute possessed by the members of the genus. Accordingly, the disclosure meets the requirements of 35 U.S.C. §112, first paragraph and withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph:

Claims 1, 3, 4, 6-8 and 32-35 were rejected under 35 U.S.C. §112, second paragraph. The Examiner objects to the phrase “equivalent or enhanced immunological response” and queries “what immunological response is being measured to determine if the response is equivalent or enhanced?” Office Action, page 6. As explained above, claim 1 has been amended to recite that the immunological response “comprises the ability to elicit the production of neutralizing antibodies against *C. parvum*.” Accordingly, this basis for rejection has been overcome.

The Examiner also objected to the reference to Figure 2B as “there are no amino acids recited at all in Figure 2B, only nucleotides.” Office Action, page 7. Applicant has amended claims 1 and 32 to refer to Figure 2A. Thus, this basis for rejection has also been overcome.

Rejection Under 35 U.S.C. §102(b):

Claims 1, 4 and 6-8 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,773,245, to Wittrup et al. (“Wittrup”). The Office argues that amino acids 461-467 of SEQ ID NO:18 of Wittrup are identical to amino acids 177-183 of SEQ ID NO:4 of applicant’s. The Office concludes “the nucleic acid disclosed by Wittrup et al is deemed to comprise an ‘immunogenic fragment’ of the claimed nucleic acid molecule.” However, applicant respectfully submits that Wittrup does not anticipate the claims.

In particular, Wittrup’s seven amino acid stretch is found within a wholly different protein than that encoded by applicant’s claimed nucleic acid sequence. In fact, Wittrup’s amino acid sequence is 504 amino acids in length. Applicant’s full-length amino acid sequence is 193 amino acids in length! Thus, contrary to the Examiner’s assertions, Wittrup does not represent a fragment of applicant’s 193 amino acid sequence.

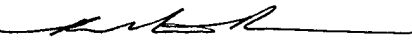
Additionally, applicant’s claims now recite the fragment comprises at least 15 amino acids. Wittrup’s region of homology includes only seven amino acids. Moreover, Wittrup’s protein does not demonstrate the requisite activity, namely, the ability to elicit the production of neutralizing antibodies against *C. parvum*. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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By: 
Roberta L. Robins
Registration No. 33,208
Attorney for Applicant

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Telephone: (650) 493-3400
Fax: (650) 493-3440